(12) UK Patent Application (19) GB (11) 2 147 506 A

(43) Application published 15 May 1985

(21) Application No 8423662

(22) Date of filing 19 Sep 1984

(30) Priority data
(31) 539723 (32) 6 Oct 1983 (33) US

(51) INT CL⁴
A62B 7/00

(52) Domestic classification
A5T CK

(56) Documents cited
None

(58) Field of search
A5T

(71) Applicant
New York University (USA–New York),
70 Washington Square South, New York, N Y 10012,
United States of America

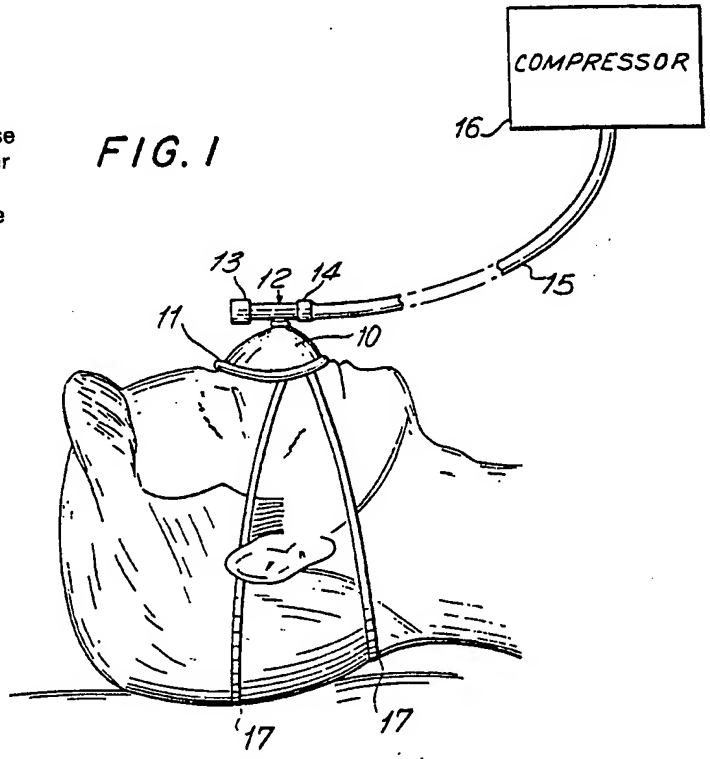
(72) Inventor
David M Rapoport

(74) Agent and/or Address for Service
Marks & Clerk,
57–60 Lincoln's Inn Fields, London WC2A 3LS

(54) Apparatus for the treatment of obstructive sleep apnea

(57) A nose mask assembly 12 for the treatment of obstructive sleep apnea which is comprised of a nose mask 10 adapted to be sealed over the nose of a patient, an inlet 15 for supplying a continuous positive pressure of air to the mask and a threshold valve 13 to release air from the mask.

FIG. 1



GB 2 147 506 A

2147506

FIG. 1

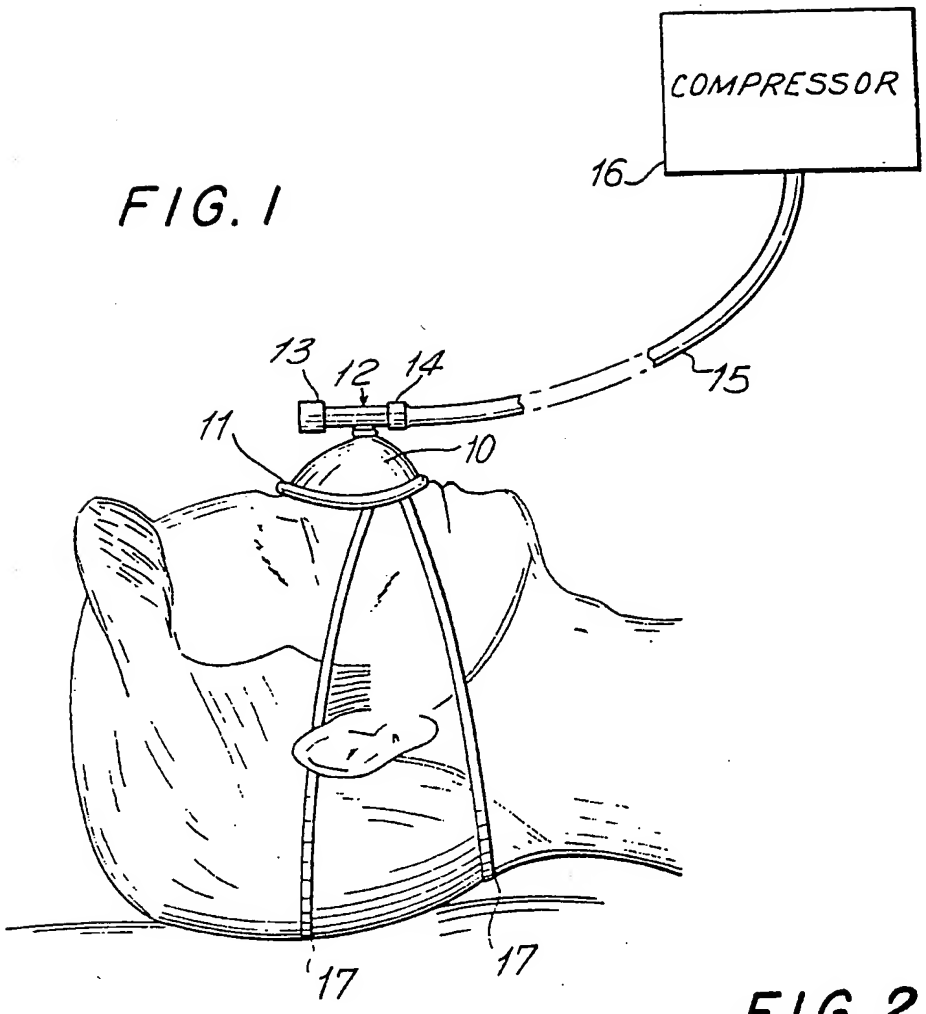
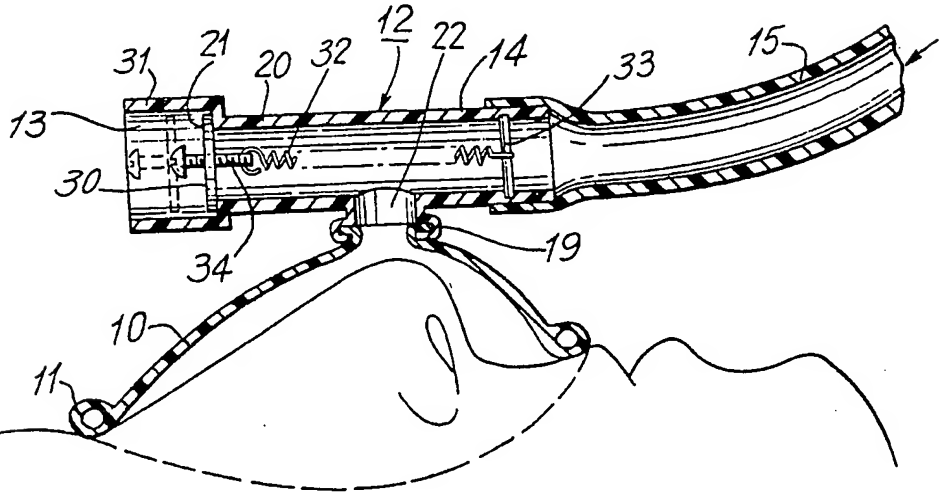


FIG. 2



SPECIFICATION

Apparatus for the treatment of obstructive sleep apnea

This invention relates to a method and apparatus for the treatment of obstructive sleep apnea, and is particularly directed to such a method and apparatus wherein a positive pressure is applied to the nares of a patient by means of a nose mask.

The syndrome of obstructive sleep apnea is a common disorder, especially in middle-aged obese males. The problem arises in sleep-induced occlusion of the oropharyngeal airway, resulting in multiple apneic occurrence during sleep. As a consequence, there is a severe interruption of sleep in the patient, and, as the disease progresses over periods of time, greater degrees of asphyxia occur. The duration of apnea may exceed two minutes, with the arterial hemoglobin oxygen saturation falling below 50 percent. The patient may be entirely unaware of the occurence of these frequent obstructions to breathing. The symptoms are generally excessive day-time sleepiness, and snoring. The nocturnal asphyxia may eventually lead to a number of further problems, such as cardiac arrhythmia, pulmonary hypertension and right heart failure, systemic hypertension, severe morning headache, intellectual and personality changes and polycythemia.

One method of treatment for the disease is a tracheostomy, which is left open at night. Medical and psychosocial problems frequently interfere with the acceptance of tracheostomy, both by the patient and the physician, and this solution has generally been employed only in severe cases. Patients have frequently choosen to accept the discomfort associated with the disease rather than have a tracheostomy.

It has been suggested that continuous positive airway pressure (CPAP) be applied to the patient, during periods of sleep, by way of the nose ("Reversal of obstructive sleep apnea by continuous positive airway pressure applied through the nares", Collin Sullivan *et al.* The Lancet, April 18, 1981, pages 862-865"). Sullivan *et al* suggest the application of low levels of pressure, in the range of 4.5 to 10 centimeters H_2O, and reported that this procedure completely prevented upper airway occlusion during sleep, allowing the patients to have entire nights of uninterrupted sleep. The continuous positive airway pressure applied in this manner may provide a pneumatic splint for the nasopharyngal airway.

In the arrangement provided by Sullivan *et al.*, two soft plastic tubes were shaped to fix snugly in each naris. The other ends of these tubes were inserted into a lightweight wide bore tube, the arrangement being strapped to the patients face. A medical grade silicone rubber was then run over the nose and nares to provide a seal. Continuous positive pressure was produced by connecting one end of the wide-bored tube to an air compressor motor with variable speed control. The other end of the wide-bore tube was led away from the patient and narrowed, to provide a mechanical resistance. The resistance of the circuit was choosen so that a high bias flow (20-40 liters per minute) was sustained for the range of pressures required at the nose.

While the CPAP procedure as reported by Sullivan *et al* may provide temporary relief, i.e., patients with severe disease may satisfactorily employ the technique for several nights, the required cumbersome physical equipment renders this solution satisfactory only for in-hospital management of patients, hence being practical only for severely affected patients. The uncomfortableness of the arrangement is not conducive to continual use by patients in the home environment.

While various masks have been employed in the past for respiration purposes, conventional respiration masks also cover the mouth, and are designed primarily for temporary use or for use with persons who do not require comfort. Such masks may be employed for anesthesia or resuscitation. A full face mask of this type is not satisfactory for patients with obstructive sleep apnea. The treatment relies on the difference in pressure between the nose and mouth to open the airway. Furthermore, leaving the mouth uncovered allows the patient to breathe normally while awake and in case of failure of the air compressor or valve. Comfort is critical since a lack of willingness of a patient to continually employ a mask during sleeping hours defeats the purpose of the treatment.

In further masks, such as provided, for example, for dental applications, the nose masks have face seals such that they can not be pressurized. Application of CPAP absolutely requires the maintenance of pressure.

The present invention is therefore directed to the provision of a method and apparatus for the application of CPAP by means of a comfortable nose mask, for the treatment of apnea, whereby patients exhibit no discomfort from the use of the mask.

Briefly stated, in accordance with the invention, the above object is achieved by provision of a nose mask incorporating a threshold valve, wherein the air pressure continually applied to the mask is continually released from the mask, by means of a valve, at such a pressure that normally some pressurized air always escapes from the mask by way of the valve. This feature serves to maintain the air pressure at the nose, in order to maintain the nasopharyngel airway open, as well as to provide a continuous flow of fresh air to the mask so that the patient may exhale through the mask, with the exhaled air being immedi-

ately exhausted through the valve.

Since the threshold valve employed in the mask in accordance with the invention may be a very simple device, it may be readily miniaturized, so that the mask assembly may be very small and lightweight, thereby being comfortable to wear. The air supply tube may be a single small very flexible tube, enabling the patient to move around at night without difficulty. The ease of movement is further enhanced by the provision of a swivel joint at the junction of the valve and mask.

In order that the invention will be more clearly understood, it will now be disclosed in greater detail by way of non-limiting example, with reference to the accompanying drawings, wherein:

Figure 1 is a view of a patient wearing a mask in accordance with the invention;

Figure 2 is a cross-section view of one embodiment of a mask assembly in accordance with the invention.

Referring now to figure 1, a generally cup-shaped nose piece 10 is provided with a rim 11 for lightly sealing the mask to the face. The rim 11 is preferably an air cuff, i.e. a flexible donut-shape member, fitted to the edge of the mask and containing a pressurized gas. It is of course apparent that other sealing rims may be employed for the mask.

The nose mask is further provided with a valve assembly 12 including a threshold valve 13 for continually relieving air within the mask at a pressure such that the valve normally not be closed in use. In addition, the assembly 12 has an extension 14 adapted to be connected to an air supply tube 15, the tube 15 receiving compressed air from a conventional compressor 16.

In order to hold the nose mask on the face of the patient, lightweight flexible straps 17 may be connected to the mask to extend around the head of the patient.

One embodiment of a nose mask in accordance with the invention is more clearly illustrated in the cross-sectional view of figure 2. In this mask, the air cuff seal 11 is of a light plastics material, and must be of a non-irritating material, since it continually contacts the face of the patient. The nose piece 11 is of a plastics material that is partially rigid and partially flexible, such as heavy vinyl, of a nature that can conform with the face. The element must be sufficiently large to accommodate the noses of all patients who may employ the mask. The partial rigidity is required so that the nose piece will generally maintain its shape in use, while still enabling it to conform to the face of the patient.

The nose piece 10 is preferably connected to the valve assembly 12 by way of a swivel joint 17. The valve assembly is comprised of a plastic tube, one end of the tube forming a valve seat 1, and the other end 14 being adapted to being interconnected to tube 15 by any conventional means. The side of the tube 20 is provided with an aperture 22 defining the swivel interconnection with nose piece 10. While any conventional swivel interconnection may be provided, it is desirable in accordance with the invention that the swivel interconnection between the valve assembly and the nose piece 10 be as short as possible, thereby to minimize the size and weight of the nose mask. The swivel interconnection minimizes danger of tangling of the tube during the night, as a result of movement of the patient.

The valve in accordance with the invention may be simply comprised of a rigid valve disk 30 held adjacent the valve seat 21. The disk 30 may be loosely axially guided at its edge by an enlarged diameter end section 31 of the tube 20. The valve disk 30 is urged toward the valve seat 21 by a spring, such as helical spring 30 extending through the tube 20 to a fixed connection, for example, to a pin 33 held to the walls of the tube. Adjustability of the threshold pressure of the valve may be effected by connecting the end of the spring 32 to the end of an adjustment screw 34 threaded in the disk 30. The adjustment of the screw thereby controls the tension of the spring, to determine the pressure within the mask. The mask may be set, for example, to have a threshold from 5 to 15 centimeters H_2O. The pressure adjustment for any patient is set so that under normal breathing conditions the valve is always open, even during inhalation. As a result, the required positive pressure is always present to maintain the nasopharyngeal airway opened. As a result of the nuse of the threshold valve in accordance with the invention, air exhaled by the patient is immediately exhausted by way of the threshold valve, without affecting contamination of the air supplied to the mask. The tube for supplying air to the mask may hence be very small and flexible. The threshold valve itself may be of very simple construction, and is adapted for miniaturization, thereby to minimize the size and weight of the mask.

The internal end of the cup-shaped element 10, is not critical, aside from being of a size sufficiently large to cover the nose of any patients, since this space is flushed in use by a large flow of air, for example, 40-50 liters per minute. The element preferably has a minimum height, however, in order to minimize the "leverage effect" of forces on the tube 15 dislodging the seal.

The compressed air may be provided by any conventional device, so that the patient may inexpensively provide this source for use at his own home. The compressed air may be heated and humidified by conventional heaters.

In the treatment of obstructive apnea, it must be stressed that the condition can be expected to continue for the remainder of the

patients life, and it can be expected to increase in severity. Accordingly, a patient seeking relief by the use of CPAP can expect to require use of the mask for the rest of his life, so that the effectiveness of treatment CPAP depends upon the willingness of the patient to use a nose mask. The nose mask should be employed during naps as well as during nighttime sleeping.

The present invention therefore solves the problem of providing the required comfortableness of a nose mask, thereby minimizing the reluctance of patients to seek relief by this means. The mask and method in accordance with the invention may be readily employed in the patients home, and provide an inexpensive solution to the problem.

While the specific threshold valve disclosed above constitutes one embodiment of the invention, the invention is not limited to this disclosed structure. Thus, other valves which enable the release of pressure at a determined threshold, in order to normally maintain a flow of pressure therethrough, may be employed.

CLAIMS

1. A nose mask assembly for the treatment of obstructive sleep apnea, the assembly comprising a nose mask adapted to be sealed over the nose of a patient, inlet means for supplying a continuous positive pressure of air to the mask, and a threshold valve to release air from the mask and having a threshold pressure to be continuously opened during normal respiration of the patient.

2. A nose mask assembly according to claim 1 wherein the threshold pressure is from 5 to 15 centimeters H_2O.

3. A nose mask assembly according to claim 1 or 2 further comprising a valve assembly, the threshold valve and inlet comprising parts of the valve assembly, and a swivel connection between the nose mask and the valve assembly.

4. The nose mask assembly according to claim 3 wherein the valve assembly comprises a generally cylindrical tube of plastic material, the threshold valve being provided at one end of the tube and the inlet being provided at the other end of the tube, a central portion of the tube defining the swivel connection to the nose mask.

5. A nose mask assembly according to any preceding claim, wherein the threshold valve comprises a valve seat coupled to exhaust air from the mask, a valve disk and a spring resiliently urging the disk toward engagement with the valve seat to provide a threshold opening pressure from 5 to 15 centimeters H_2O.

6. A nose mask assembly according to any preceding claim, wherein the nose mask comprises a flexible cup-shaped element adapted to fit over the nose of a patient and having an air-cuff edge for sealing to the face of the patient.

Printed in the United Kingdom for
Her Majesty's Stationery Office, Dd 8818935, 1985, 4235.
Published at The Patent Office, 25 Southampton Buildings,
London, WC2A 1AY, from which copies may be obtained.